EPA RESPONSE TO LOWER WILLAMETTE GROUP OPENING SUBMISSION, dated September 21, 2012.

## I. INTRODUCTION

Ten parties[1] signed the Administrative Settlement Agreement and Order on Consent for Remedial Investigation/Feasibility Study, U.S. EPA Docket Number CERCLA-10-2001-0240, which became effective on September 28, 2001 ("AOC"). The AOC was amended on June 16, 2003 and April 27, 2006. [2] The primary objective of the AOC is for the performance of a Remedial Investigation ("RI") and Feasibility Study ("FS") for the Portland Harbor Superfund Site and reimbursement of government oversight costs. The AOC and Statement of Work ("SOW") are attached as Exhibit 1.

Section IX. of the AOC provides the process for approvals and modifications of deliverables produced under it. In accordance with that Section, EPA has the right to "comment on, modify, and direct changes for all deliverables in writing." *See* AOC, Section IX, Paragraph 1. Additionally, ". . . Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables …." *Id.*

Respondents were required to produce a Baseline Human Health Risk Assessment ("BHHRA") under the AOC and SOW to be approved by EPA. *See* AOC Section VIII and Task 5 of the SOW, Section 7.8.3. The first draft BHHRA was submitted to EPA on September 23, 2009, Exhibit 2 hereto. EPA extensively commented on the first draft BHHRA over a span of about eight months, *see* Tabs 5, 7, and 8.[3] Additional comments were provided after the July 2010 comment set, *see* Tabs 6, 10, 12, 13, 14, 23, and Exhibit 3.[4] Meetings were conducted to discuss EPA's comments by issue category, rather than by specific comment, *see* Tabs 9 and 11. The meeting discussions were focused on the comments that the Respondents had issues or questions

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[1] The ten signatories to the AOC are: ATOFINA Chemicals, Inc. (now Arkema, Inc.), Chevron U.S.A. Inc., Gunderson, Inc., Northwest Natural Gas (now NW Natural), City of Portland, Port of Portland, Time Oil Co., Tosco Corporation (now ConocoPhillips Co.), Union Pacific Railroad Company, and Oregon Steel Mills, Inc.

[2] The 2003 and 2006 AOC amendments did not change the order provisions relevant to this dispute and, therefore, will not be further explained or discussed in this Response.

[3] References to Tabs are to the Supporting Documentation for the September 21, 2012 Lower Willamette Group Opening Submission. Additional supporting documentation being submitted by EPA is attached to this Response Brief as Exhibits.

[4] The record clearly shows that a series of comments and responses on the draft BHHRA were ongoing from December 2009 until April 11, 2011; therefore, Respondents' contention that EPA's July 2010 comprehensive comment set was the last and final comments they expected from EPA on the second draft BHHRA is not reasonable. Also wholly unreasonable, is Respondents' interpretation of EPA's use of the phrase "comprehensive comments set" in that July 2010 letter to mean that EPA would not provide any comments or seek any more changes to their next draft of the BHRRA.

about. The Respondents produced tables with summaries of the understandings reached in the meetings or otherwise how they intended to address some, but not all, of the comments, *see* Tabs 9 and 11. On each table, EPA reviewed their summaries and generally agreed with the approach proposed, but clearly stated that EPA would have to see the revised document before determining whether all comments were addressed.[5]

The second draft BHHRA was submitted to EPA for review and approval on May 2, 2011, *see* Tab 15. After EPA's initial review of the document, EPA notified the Respondents on July 21, 2011 of the intent to modify the BHHRA and requested all word files of the document, *see* Tab 18. The Respondents immediately contacted EPA project managers for fear of EPA work takeover. EPA subsequently sent an email on July 22, 2011, *see* Tab 19, clarifying its intent to modify the document and not take over the document. On June 22, 2012, consistent with the AOC (Section IX, Paragraph 1), EPA transmitted to the Respondents its modified BHHRA text, directing them to accept the modified text and to make necessary changes to tables and figures, *see* Tab 16.

The AOC, Section XVIII., Paragraph 1, provides a dispute resolution process to the Respondents for "[a]ny disputes concerning activities or deliverables required under this Order…." On July 27, 2012, the Respondents notified EPA that it was disputing EPA's modifications made to their second draft BHHRA, *see* Tab 22. In accordance with the dispute resolution process, informal discussions occurred starting on July 27th with the hope of resolving the dispute. EPA is pleased that many issues initially raised by Respondents have been resolved, *see* Tables 1 and 2. The informal dispute resolution process was successful in narrowing down the issues significantly. Unfortunately, not all of the Respondents' issues were resolved to their satisfaction.

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[5] Tab 10, EPA's letter, dated September 22, 2010, states: "EPA has reviewed the September 15, 2010 letter and attachments and agrees, with clarifications, that EPA's directed comments on the BERA and BHHRA should be revised in accordance with the general framework, and that the proposed resolution described in LWG's general responses matches our understanding of the meeting outcome. . . . **Because we did not discuss all the directed comments, a final determination that the LWG has addressed the directed comments can not be made until a redline-strikeout version of the BERA and BHHRA reports are submitted (emphasis added).**"

Likewise, Tab 11, EPA's letter, dated November 18, 2010, states: "EPA has reviewed the LWG responses, as summarized in the tables, and has determined that the vast majority of issues associated with addressing EPA's comments have been resolved. However, there were three comments for which the LWG did not agree to make the specified changes. These comments are related to the conceptual site model (Linking Sources to In-Water Contamination), the data lockdown date, and the inclusion of the PBDE fish tissue data in the BHHRA. EPA has determined that these comments must be addressed to complete the RI and BRA Reports, and hereby directs the LWG to revise the draft RI and BRA Reports as described in Attachment 1. . . . **Because we did not discuss all of the comments or details on how the individual comments will be addressed, a final determination that the LWG has addressed the directed and non-directed comments can not be made until redline-strikeout versions of the RI and BRA Reports are submitted (emphasis added).**"

EPA's actions and decisions regarding the draft BHHRA have all been in accordance with the review and approval process set forth in the AOC that the Respondents agreed to and which is the operative document that provides the process and roles and responsibilities of EPA and the signatories. The Respondents characterize EPA's modification of their second draft BHHRA as "a defining moment" that will have "ramifications far beyond the document itself." Opening Statement page 2. Although we can't refute that they may have these feelings, given the clear language of the AOC and the review and approval process set forth therein, there is no reasonable basis in law or fact that supports Respondents' arguments that EPA acted arbitrarily or capriciously in modifying the BHHRA. There too is no reason for the AOC to be amended to add a "set of documented protocols to guide better working relationship between the [Respondents] and EPA…." Opening Statement page 3.

EPA acknowledges the significant work and effort that Respondents have put forth to get the RI and FS to where it is today. We want to emphasize to the Director and to the other potentially responsible parties who will be asked to participate in the remediation of the Portland Harbor Superfund Site that EPA's modifications were to the text of BHRRA. EPA had no problems nor did we change the calculations or analysis that made up the majority of the work and effort doing the risk assessment. In fact, most of the Respondents' words were retained by EPA, but moved to other locations and/or redundancies eliminated. EPA's modifications to the text were made, as we have stated numerous times, to make the document more clear, transparent, and consistent with EPA guidance. Given the importance of this analysis and its role in future remedy decisions, it is imperative that the document be clear as possible regarding the major assumptions and conclusions. That is not to say, however, that the entire risk assessment process undertaken by Respondents was inadequate. We have never said it was. Anyone who reads the back and forth on this dispute must conclude that EPA's modifications to the BHHRA did not change, revise, or eliminate the majority of Respondents' work on the human health risk assessment.

The EPA took two separate actions related to the Respondents' second draft BHHRA. First, as early as July 2011, EPA decided to modify the second draft BHHRA in order to have an approvable final BHHRA as quickly as possible, *see* Tabs 18 and 19.[6] On June 22, 2012, EPA provided the modified BHHRA to the Respondents and took its second action, which was to

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[6] EPA's letter to Respondents, dated July 21, 2011, notified them that "EPA has the right to modify any deliverables under the AOC, which EPA intends to do with the BHHRA. Consequently, EPA is requesting all the original document (Word, Excel, etc.) files used to create the BHHRA so that we can modify the document." EPA's email to LWG, dated July 22, 2011 further clarified that "EPA believes that there are changes needed to some of the language and presentations in the document, and it will be most efficient for EPA to mark up the document with those specific changes rather than provide additional comments that would then lead to further back and forth (comment & revision cycles) between EPA and LWG. The intent is to expedite the process by providing an approvable red-lined document that the LWG could then finalize."

notify the Respondents' that their second draft was inadequate and did not fully reflect EPA's directions for changes in compliance with the notice requirements of Section XIX., Paragraph 1 of the AOC. EPA's second action began the accrual of stipulated penalties, but EPA has not assessed penalties yet. The two actions are separate and distinct. EPA has the authority to comment on, modify, and direct changes to any deliverable whether or not the Respondents are determined to be violation of the AOC. Likewise, EPA may determine that Respondents have not complied with the AOC but does not have to modify the offending document. In this dispute, the Respondents dispute both EPA's noncompliance determination and a few technical issues related to the modified BHHRA. They also dispute the process EPA used in taking its actions.

EPA will respond to the specific issues raised by Respondents in the remainder of this response document. Based on our responses and the administrative record created for this dispute, EPA respectively requests the Director to make the following decisions:

1. Uphold EPA's determination under the AOC that Respondents failed to produce a deliverable of acceptable quality, or otherwise failed to perform in accordance with the requirements of the AOC because they did not adequately address all of EPA's comments;
2. Adopt EPA's positions, as presented in this response, on the appropriate Reasonable Maximum Exposure and Central Tendency Exposure Scenarios for recreational and subsistence fishers for incorporation, as appropriate, into the text and tables and figures of the final BHHRA;
3. Agree with EPA's positions on exposure scenario and uncertainty language regarding domestic water and clam consumption (which would require no additional changes to the draft BHHRA text);
4. Agree with EPA's positions regarding the Executive Summary, Table of Contents, and Conclusion sections;
5. Adopt the revised BHHRA, dated September 17, 2012, [Respondents' Exhibit 1 and EPA's Exhibit 13] which incorporates a majority of the resolutions reached between Respondents and EPA as of September 14, 2012, and require that the resolutions of the disputed technical issues (2, 3, and 4, above) from this dispute will be incorporated, if necessary, by EPA into the final document[7]; and
6. Determine that the Respondents' request to establish protocols for better working relationships would be an amendment to the review and approval process and

[7] EPA agrees that substantial progress was made during the informal dispute process and that Tables 1 and 2 generally reflect the specific issues raised by Respondents that they and EPA reached some form of resolution on. But it is only the specific agreed-upon language reflected in the red-lined text of the Sept 17, 2012 BHHRA that has been agreed to so far. Thus, EPA does not believe it is necessary or appropriate for the Director to approve Tables 1 and 2 themselves.

enforcement provisions of the AOC and, thus, is not relief that can be addressed through the dispute resolution process.

## II. EPA'S MODIFICATION OF THE RESPONDENTS' SECOND DRAFT BHHRA COMPLIED WITH THE AOC REVIEW AND APPROVAL PROCESS.

Since the AOC is the controlling document for judging the process and circumstances surrounding EPA's modification of the BHRRA and noncompliance determination, it is important to highlight the most relevant provisions contained in it. By signing the AOC, the Respondents agreed to the process put forth in the AOC. EPA will describe below how it used and complied with the process prescribed in the AOC with respect to the BHHRA deliverable.

Section II, Paragraph 2, of the AOC states:

> "Respondents agree to undertake all actions required by this Consent Order. In any action by EPA or the United States to enforce this Consent Order, Respondents consent to and agree not to contest the authority or jurisdiction of EPA to issue or enforce this Consent Order, and agree not to contest the validity of this Order."

Section IX, Paragraph 1, of the AOC states:

> "EPA reserves the right to comment on, modify, and direct changes for all deliverables in writing . . . EPA will meet with the Respondents in an effort to resolve disputes. At EPA's discretion, Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA either in subsequent or resubmitted deliverables within a time frame specified by EPA."

Section XIX., Paragraph 1, of the AOC provides:

> ". . . for each day that Respondents fail to complete a deliverable in a timely manner or fail to produce a deliverable of acceptable quality, or otherwise fail to perform in accordance with the requirements of this Order, Respondents shall be liable for stipulated penalties. . . .Where a revised submission by Respondents is required, stipulated penalties shall continue to accrue until a satisfactory deliverable is produced. EPA will provide written notice for violations that are not based on timeliness; nevertheless, penalties shall accrue from the day a violation commences."

The Respondents were required to produce a Baseline Human Health Risk Assessment as a deliverable under the AOC and SOW to be approved by EPA, *see* AOC Section VIII and Task 5 of the SOW, Section 7.8.3. The Respondents provided a draft final BHHRA on May 2, 2011, after significant commenting occurred on its first 2009 draft and several meetings were conducted on those comments, as discussed above.

As plainly reserved in the AOC, the EPA chose to modify this version of the BHHRA to fix the readability and objectivity of the document and better justify the basis for specific assumptions used in the BHHRA.[8] The EPA also modified the document to include an RME for recreational fishers and subsistence fishers to comply with CERCLA's mandate that remedial actions be protective of human health and the environment[9] and be consistent with EPA guidance.[10] In a letter dated July 21, 2011, and in a follow-up email on July 22, 2011 (*see* Tabs 18 and 19), EPA notified the Respondents of its intent to modify the BHHRA document, although notice is not required by the AOC.

Also consistent with the AOC, EPA found that there were at least 17 comments that were not adequately addressed as required by the AOC and notified the Respondents in its June 22, 2012 letter that they were out of compliance with the AOC. The AOC provides that stipulated penalties begin to accrue from the date of noncompliance until compliance is achieved and EPA's noncompliance notice merely reiterated what the AOC says.

The Respondents contend EPA was arbitrary and capricious in finding them out of compliance and claim we did so to coerce them to accept our modifications. The EPA was not being coercive, but rather utilizing the enforcement options that are clearly laid out in the AOC to achieve a final BHHRA as soon as possible. Penalties accrue until a satisfactory document is produced so there is an incentive for parties to complete documents expeditiously. Furthermore, Section XIX, Paragraph 1, also provides that in determining whether to waive imposition of penalties EPA can consider the Respondents' good faith attempts to comply or timely correction of defects. The Respondents were fully aware of EPA's discretion in this area, and now cannot cast EPA as being coercive in using its enforcement authorities to achieve a satisfactory, final document.

Section IX, Paragraph 1, of the AOC states that "EPA will meet with Respondents in an effort to resolve disputes." In EPA's June 22, 2012, letter, *see* Tab 16, EPA project managers offered to coordinate and discuss questions the Respondents had with the required changes to the BHHRA. On July 17, 2012, at the request of Bob Wyatt and Jim McKenna, EPA staff, Chip Humphrey, Kristine Koch, and Elizabeth Allen, had a conference call to discuss the modified BHHRA. During that call, the Respondents indicated that they were "not trying to resolve anything" and "wanted to talk about LWG's reactions" to the BHHRA comments. They requested EPA do two things or they would dispute the changes: 1) retract the determination of noncompliance; and 2)

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[8] A consistent comment EPA gave to Respondents' starting with comments on their Round 2 characterization report was that discussions of risk needed to be objective and unbiased. *See* Exhibits 10 and 11.

[9] 42 U.S.C. § 9621(b)(1) and 40 CFR §§300.430(a)(i) and (e)(9)(iii)(A).

[10] EPA/540/1-89/002, OSWER Directive 9355.0-30, OSWER Directive: 9285.6-03, OSWER Publication 9285.7-081, EPA/600/P-95/002Fa-c, EPA 823-B-97-009, EPA-821-R-00-025, EPA 823-B-00-007, EPA-822-B-00-004, Office of Emergency and Remedial Response, Publication 9285.7-47, EPA 540-R-02-002, OSWER 9285.6-10, EPA 821-C-02-003, OSWER Directive 9285.7-53, EPA/630/R-03/003F, and EPA/600/R-09/052F (other relevant guidance is cited in the reference section of the BHHRA).

retract the directive changes to the BHHRA. They also stated that further discussions would not stop the Respondents from disputing the required changes. Since EPA was not willing to retract the directive changes to the BHHRA, the Respondents chose to invoke dispute resolution in accordance with Section XVIII of the AOC on July 23, 2012. Between July 23, 2012, and September 14, 2012, the Respondents and EPA had several meetings in an attempt to informally resolve the Respondents' dispute issues, *see* Tables 1 and 2, and were successful in resolving all but the three technical issues the Respondents raises in this formal dispute.

## III. RESPONDENTS DID NOT COMPLY WITH THE AOC BECAUSE THEY DID NOT FULLY CORRECT ALL DEFICIENCES AND INCORPORATE ALL COMMENTS SUPPLIED BY EPA.

On June 22, 2012, EPA notified the Respondents that they failed to produce a BHHRA of acceptable quality, or otherwise failed to perform in accordance with the requirements of the Order by failing to fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA on prior versions of the BHHRA, *see* Tab 16. On July 17, 2012, Respondents' representatives and EPA staff had a conference where Respondents requested EPA do two things or they would dispute the changes: 1) retract the determination of noncompliance; and 2) retract the directive changes to the BHHRA. Since EPA was not willing to retract the directive changes to the BHHRA, the Respondents chose to invoke dispute resolution in accordance with Section XVIII of the AOC on July 23, 2012(*see* Tab 21). Consequently, EPA provided the Respondents with the basis for noncompliance on July 27, 2012 (*see* Tab 22), since that would be part of their dispute.

In EPA's review of the draft final BHHRA, EPA determined that several of its comments were not adequately addressed or incorporated into the document. Section IX, Paragraph 1, of the AOC states that "At EPA's discretion, Respondents must fully **correct all deficiencies and incorporate and integrate all information and comments supplied by EPA** either in subsequent or resubmitted deliverables within a time frame specified by EPA." (emphasis added). The EPA clearly stated in its transmittal of comments in July 2010 on the BHHRA (*see* Tab 7) its direction that "EPA expects the LWG to address all of the comments." EPA further repeated this direction in its letter on December 8, 2010 (*see* Tab 12) in stating "[h]owever, EPA believes that addressing all directed comments and non-directed comments consistent with previous direction and agreements, and the direction and clarifications in this letter and attachment, should resolve EPA's RI and BRA Report comments."

The EPA agrees that it is our initial burden to prove a violation of the AOC. However, the AOC sets a very, strict standard for the Respondents, i.e., "correct all deficiencies and incorporate and integrate all information and comments supplied by EPA . . . ." Thus, by its express terms, if just one comment is not addressed, the Respondents have not complied with Section IX., Paragraph 1 of the AOC, and stipulated penalties begin to accrue until the deficiency is corrected. In this case, the EPA identified 17 comments and/or issues that the Respondents did not address

adequately. Attached as Exhibit 6 to this Response is EPA's detailed recitation of the EPA's rationale for why these comments were not fully incorporated or addressed in the draft final BHHRA with additional discussion responding to Respondents' arguments. We believe that the information contained in Exhibit 6 meets our burden for proving that the Respondents did not comply with the AOC.

The Respondents argue that only directed comments versus non-directed comments[11] can be a matter for noncompliance. But such limitation or qualification is found nowhere in the AOC itself, and in fact, would directly contravene Paragraph 1 of Section IX that requires all deficiencies and comments to be addressed. To support their position, the Respondents culled the phrase "EPA's directions for changes" from Paragraph 4 of Section IX.,[12] which speaks to what actions or enforcement options EPA has if it disapproves a revised report or if subsequent submittals do not fully "reflect EPA's directions for changes." However, it is not reasonable to read that paragraph as limiting EPA enforcement to only directed changes, because it is inconsistent with other provisions of the AOC, particularly, Paragraph 1 of the same Section. Rather, the phrase, "directions for changes", in Paragraph 4 logically must be read as an abbreviated restatement of "**correct all deficiencies and incorporate and integrate all information and comments supplied by EPA"** found in Paragraph 1. The EPA clearly stated in its transmittal of comments in July 2010 on the BHHRA (*see* Tab 7) and in its letter on December 8, 2010 (*see* Tab 12) that its direction was that EPA expected the Respondents to address all of the comments provided by the EPA. Additionally, Section XIX. of the AOC regarding stipulated penalties contains no language that limits EPA's enforcement authority to a particular type of comment, such as only directed comments.

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[11] The AOC does not define or provide for directed comments versus non-directed comments explicitly. The process of reviewing deliverables that has developed between EPA and Respondents over time has led to more specific descriptors provided by EPA to its comments, such as "clarifying comments" or "directed changes." Likewise, resolving disagreements over comments and directed changes included frequent meetings between EPA and LWG technical staff and project managers. For major deliverables, the process often involved use of comment resolution tables to track, and narrow the list of disagreements. In many cases, agreements were reached through the comment resolution process, the Respondents modified the documents in accordance with EPA's comments and direction, and documents were subsequently approved. When it became apparent that agreements on certain issues could not be reached, EPA would direct the Respondents to make the changes or Respondents would request EPA to direct them so they could reserve their disagreement. EPA typically was more "directive" in requiring changes after allowing the Respondents the opportunity, or in some cases multiple opportunities, to modify unacceptable documents to correct deficiencies.

[12] Section IX, Paragraph 4 of the AOC states that "If LWG amend or revise a report, plan, or other submittal in response to EPA comments, and EPA subsequently disapproves of the revised submittal, or if such subsequent submittals do not fully reflect EPA's directions for changes, EPA retains the right to seek penalties, perform its own studies, complete the RI/FS (or any portion of the RI/FS) under CERCLA and the NCP, and seek reimbursement from LWG for costs, and/or seek any other appropriate relief."

The fact that this is the first time the EPA has made the determination of noncompliance is irrelevant to whether the Respondents failed to address all comments on the draft BHHRA. The EPA's decision not to take an enforcement action previously does not raise the standard of what is a violation of the AOC nor can it be deemed a waiver of our right to bring a future enforcement action. In addition, the AOC provides EPA with enforcement discretion in determining whether or not Respondents must fully correct all deficiencies and incorporate and integrate all information and comments supplied by EPA in a revised deliverable or in another future document (Section IX, Paragraph 1) and to whether or not to waive imposition of penalties considering the Respondents' good faith attempts to comply or timely correction of defects (Section XIX, Paragraph 1).

The record (*see* Exhibit 6) is clear that the Respondents' second draft BHHRA did not address "all deficiencies and incorporate and integrate all information and comments supplied by EPA" and thus, is in violation of the AOC. If the Director finds that EPA has proven that one or more comments or direction for change was not adequately addressed or incorporated, then, by the terms of the AOC, the Respondents are in noncompliance. However, in the future, when the BHHRA is finalized, agency discretion may be applied in determining whether to assess stipulated penalties and, if so, whether to assess an amount less than the full stipulated amount.

## IV. EPA'S TECHNICAL POSITIONS ON THE BHHRA ARE SCIENTIFICALLY JUSTIFIED AND CONSISTENT WITH CERCLA, THE NCP, AND EPA GUIDANCE

### A. EPA's positions on the Reasonable Maximum Exposure for recreational and subsistence fishers are reasonable and appropriate for the Portland Harbor Superfund Site and consistent with EPA guidance. It is not necessary to further delay the RI/FS schedule to engage in more discussions regarding the RME for these receptors.

#### 1. History of RME and CT Discussion between EPA and Respondents.

Beginning in at least 2003, EPA and Respondents had extensive discussion on the fish consumption rates as well as other variables for the risk assessment. The consumption rates to be used in the risk assessment were established as far back as 2004. The Respondents want to go back to square one on many of these issues. However, there is substantial support in the record for maintaining the consumption rates used in the risk assessment and determining the RME and CT for recreational and subsistence fishers.

Respondents provided a draft Programmatic Work Plan on March 31, 2003, and subsequently submitted proposed fish consumption rates for the Portland Harbor human health risk assessment on May 9, 2003 (*see* Tab 26). The EPA provided comments on the draft Programmatic Work Plan on July 25, 2003 (*see* Tab 33). In that letter, EPA noted that comments on the May 9, 2003 proposed fish

consumption rates would be provided at a later date, but stated that there were significant issues with Respondents' RME for fish consumption.

Respondents requested a schedule extension on the Programmatic Work Plan on October 15, 2003 (Exhibit 7) and subsequently provided a draft final Programmatic Work Plan to EPA on November 10, 2003, Exhibit 8. On February 11, 2004 (*see* Tab 27), EPA further commented on the Programmatic Work Plan and provided direction on fish consumption rates. On February 23, 2004, the Respondents sent a letter (Exhibit 9) which indicates that a meeting was to be held on March 3, 2004, and that fish consumption rates were to be discussed.

EPA sent a conditional approval letter to the Respondents on March 15, 2004, (*see* Tab 47). In the letter, Condition 3 (Text changes to the RI/FS Work Plan) specified that the included text changes were based on review of the February 27, 2004, and March 5, 2004, redline versions of the Work Plan, discussion and agreements during the March 3, 2004 meeting, and subsequent discussions between the EPA and the Respondents. Specific comments on fish consumption rates were provided in the comments for Appendix C, Section 3.4.3. It was clear at this point that both parties agreed that consumption rates would not be designated as representing either RME or CT exposures and that a range of consumption patterns for fishers using the ingestion rates of 17.5 g/day, 73 g/day, and 142 g/day would be used for adult consumption. These consumption rates were anticipated to represent average to high end ranges of fish consumption for the recreational and subsistence fishers.

As the record shows, there was significant debate and disagreement regarding fish consumption rates and even what to name the various fisher categories. To keep the process moving forward, EPA agreed that Respondents did not have to identify RME for the fisher receptors in their drafts of the BHHRA.

2. Basis for EPA Determining that the BHHRA Needed to be Modified to Include an RME for Recreational and Subsistence Fish Consumption.

Both the NCP and EPA guidance are clear that the risk assessment should present an assessment of reasonable maximum exposure. The preamble to the NCP states that "In the Superfund program, the exposure assessment involves developing reasonable maximum estimates of exposure for both current land use and potential future land use conditions,[13]" while RAGS Part A notes that "actions at

[13] 55 Fed Reg. 8666 at 8710 (*see* Tab 30).

Superfund sites should be based on an estimate of the reasonable maximum exposure expected to occur under both current and future land-use conditions."[14]

Therefore, to be consistent with both national policy and EPA's human health risk assessment guidance and to have a clear and transparent record to establish that the selected remedy is protective of human health, an RME for recreational and subsistence fishers needs to be identified. EPA's modifications to the BHHRA did so.

EPA's modified version of the BHHRA (*see* Tab 16) utilized the Respondents' calculations to the greatest possible extent while meeting the intent of our February 2004 direction on fish consumption which clearly noted that the 17.5 g/day represented a central tendency value, and that 73 g/day and 142 g/day represented higher end (~95$^{th}$ percentile) consumption rates for the recreational fisher and the non-tribal high fish consumers, respectively. Semantics aside, these descriptions clearly fit the definitions of CT and RME.

3. EPA's Definition of RME is Consistent with Guidance and National policy.

The Respondents claim that it is inconsistent with guidance and national policy to designate a specific ingestion rate as the RME versus the overall exposure pathway. However, there is nothing in EPA guidance or policy to support the conclusion that RME must be defined only as a pathway. As noted, EPA's June 22, 2012, redlined BHHRA (*see* Tab 16) made a distinction that for different receptors (recreational versus subsistence fishers) different consumption rates represented CT and RME variables for contact rate. RAGS Part A (Section 6.4.1) provides that when evaluating RME, both the contact rate and exposure frequency and duration should approximate 95$^{th}$ percentile or upper-bound values. Thus, the designation of specific consumption rates as representing RME values is not the same as stating that the intake alone represents RME, but rather the consumption rates represent specific components of an overall assessment of RME.

EPA's June 22, 2012 redlined BHHRA (*see* Tab 16) deleted the evaluations of fish consumption which used the simple arithmetic mean as the exposure concentration. This is consistent with EPA guidance[15] which defines the exposure concentration as a central tendency value represented by the 95 percent upper confidence limit on the arithmetic mean. Also consistent with EPA guidance, upper-bound (95$^{th}$ percentile) values were used to represent exposure duration

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[14] RAGS Part A Section 6.1.2 p. 6-4, (*see* Tab 29)
[15] RAGS Part A Section 6.4.1 p. 6-19 (see Tab 29)

(since consumption rates are presented as long-term averages as g/day, the exposure frequency is inherent in the contact rate). Thus, EPA's designation of RME fish consumption scenarios in the June 22, 2012 revised BHHRA are consistent with guidance.

Further, the argument that exposure should not be evaluated on spatial scales smaller than the defined site boundaries has no rational basis. EPA guidance is clear that exposures should be evaluated based both on the chemical distribution at the site, and the location and activity patterns of the potentially exposed populations. Ample precedence is available from other Superfund risk assessments that evaluate RME on the basis of operable units or distinct sources and areas of contamination, rather than on an overall site-wide basis.

During the informal dispute process, discussions on the RME occurred and EPA agrees some adjustments to its original RME for recreational and subsistence fishers is appropriate. The Respondents provided a RME proposal on August 29, 2012 (presented herein as Exhibit 16), EPA presented its revised RME proposal to the Respondents on September 11, 2012 (included herein as Exhibit 17), but Respondents dispute our proposal and have requested to have further discussions on the issue. Both proposals utilized the information currently existing in the BHHRA rather than requiring a re-evaluation of exposure values. We maintain that these issues have been debated for over ten years and there is sufficient information to support EPA's RME proposals and finalize the BHHRA. The Director should find that the current RME proposal is adequate for the Portland Harbor BHHRA and should be incorporated into the final BHHRA.

4. Significant Components of EPA's Recreational and Subsistence RME Proposal for Incorporation into the Final BHHRA.

Summarized below, the significant components of EPA's proposed RME for recreational and subsistence fishers are as follows:

EPA has identified two different non-tribal receptor populations, recreational and subsistence (or high-consuming) fishers, distinguished primarily on consumption rates and practices. This is acknowledged in the Programmatic Work Plan, *see* Tab 1. Consistent with other exposures evaluated in the BHHRA, recreational fishers will be evaluated for both CT and RME. Subsistence fishers are evaluated for RME only, because central tendency exposures for this high-consuming population are adequately described by the RME evaluation for recreational fishers.

Fish Tissue Consumed: Recreational fishers will be based on consumption of fillet with skin, which is consistent with the results of numerous fish consumption

surveys indicating that recreational sport fishers primarily consume only the fillet portion of the fish. This is also consistent with the existing data for Portland Harbor, which includes contaminant concentrations in the fillet. Subsistence fishers will be evaluated assuming both fillet with skin consumption, as well as whole body. Assuming whole body consumption accounts for the varying consumption practices among the various cultures that supplement their diet by fishing, and for different preparation techniques, which include consumption of other parts of the fish including the head, or using the whole fish to prepare soups. EPA acknowledges that consumption of the entire fish may not represent a common practice, but that the degree to which whole body data may overestimate intake should be assessed as an uncertainty. This is consistent with RAGs Part A, Section 4.5.6.

Species Consumed: Both recreational and subsistence fishers are assumed to consume a multi-species diet, consisting of resident fish. An evaluation of the risks associated with migratory fish is not informative as to the risks associated with contamination within Portland Harbor. The multi-species diet of resident fish will be evaluated using the existing fish tissue data and assuming equal proportions of the four resident fish for which data are available.

Exposure Area: Recreational fishers will be evaluated on both a harbor-wide scale and on a smaller exposure area approximating each river mile. Harbor-wide exposures will provide a more generalized assessment of the risks associated with fish consumption at Portland Harbor; however, an assessment on a river-mile basis will inform the risks associated with the heterogeneous contaminant distribution in sediment reflecting distinct sources and associated release areas and the fact that most fishers are unlikely to uniformly fish throughout the entire 10-mile long site. Further, many fishers likely repeatedly frequent the same area either from habit, past fishing success, or accessibility. Not all fishers have access to all areas of the river through the use of boats, and some may rely on public transportation and primarily access areas located closest to bus lines.

In order to utilize the existing results to the greatest possible extent, EPA proposes using the data from Smallmouth bass as a surrogate for a multi-species diet assessed per river mile. Smallmouth bass represent the only species for which tissue data is available by river mile. Of the four resident species for which tissue data are available, measured contaminant concentrations are generally greater in Common carp and Brown bullhead, and less in Black crappie. Thus, Smallmouth bass present an appropriate means to assess risks associated with fish consumption by river mile.

Fish Consumption Rates: The technical justification for the consumption rates for both recreational and subsistence fishers is well documented in Section 3.5.10.6 of the Sept 17, 2012 BHHRA. As proposed by the Respondents during the informal dispute, *see* Exhibit A, the use of 17.5 g/day as a RME estimate for recreational consumers is unsupported. As noted in Section 3.5.10.6 of the BHHRA, the rate of 17.5 g/day is representative of the general U.S. population and not that portion that regularly consumes fish. The corresponding 90$^{th}$ percent consumption rate for consumers only is 200 g/day. EPA's Ambient Water Quality Guidance describes 17.5 g/day as an "average" consumption rate for recreational sport fishers. The use of this value rather than the corresponding 200 g/day rate accounts for the likelihood that recreational fishers consume more than just resident fish, and that not all fish consumed are caught within Portland Harbor. EPA acknowledges that the national consumption include shellfish, which account for as much as 40 percent of the overall consumption rates. However, given that the range between 17.5 g/day and 200 g/day is quite large, and the precise consumption of locally-caught fish by recreational fishers at Portland Harbor either currently or in the future is unknown, the assumption of 17.5 g/day as a central tendency estimate is reasonable and within the plausible range of uncertainty.

EPA also acknowledges the limitations and technical issues associated with the rate of 73 g/day from the Columbia Slough survey as representing a RME consumption rate for recreational fishers. The Columbia Slough survey was clearly a survey of fishers, but does not designate whether the fishers were recreational or subsistence. EPA disagrees with the Respondents' conclusions that this study is of subsistence fishers because of the apparent ethnic background of those surveyed. However, use of this survey falls within the recommended hierarchy of giving preference to surveys conducted within the local area or region (*see* Tab 42). Assuming fillet-only consumption and that 30 percent of the total weight of the fish is consumed, the corresponding rate is 29 g/day. This value is approximately within a factor of 2 of the 73 g/day value proposed by EPA. Thus, any revisions using a lower consumption rate than the 73 g/day as proposed would have minimal effect on the corresponding risk estimates for recreational fishers.

5. EPA's Proposed RME is Well Defined and Further Discussions are not Warranted and Would Only Delay Progress.

There is no basis to further delay the Portland Harbor project to conduct yet another review of the same "available guidance, fish consumption surveys from other freshwater systems and other Superfund sites to determine a recommended fish consumption rate." These issues were discussed for two years during the

Programmatic Work Plan development. The Respondents have not presented any new information that shows the fish consumption rates are unreasonable for the Portland Harbor Superfund Site. Also, contrary to Respondents' premise, EPA has tracked new studies and information issued over the years that might inform the risk assessment for Portland Harbor and find nothing leads us away from these rates but rather further supports their reasonableness.

EPA's Exposure Factors Program regularly conducts exhaustive reviews of the available literature to establish recommended exposure factors. As described in Chapter 10 of the 2011 Exposure Factors Handbook (Exhibit 19), only a single survey of freshwater recreational anglers was found from the Pacific Northwest (*see* Table 10-5 of Exhibit 19). The 95$^{th}$ percentile consumption rate was 42 g/day for recreational fishers in Lake Sammamish, Lake Washington, and Lake Union. A Washington Dept of Ecology Technical review (*see* Exhibit 20) of fish consumption rates for marine recreational fishers in King County revealed 95$^{th}$ percentile consumption rates from 42 g/day to 221 g/day. A statistical analysis of the national consumption rates presented in the Centers for Disease Control's 2003-2006 National Health and Nutrition Examination Survey (NHANES) designed to account for the relatively short reporting period reports the 90$^{th}$ and 99$^{th}$ percentile consumption values of finfish for consumers only as 115 g/day and 217 g/day. *see* Exhibit 18. An additional evaluation based on the rate of licensing in Washington as an estimate of locally harvest fish provides consumption rates of finfish at 43 g/day at the 95$^{th}$ percentile and 72 g/day at the 99$^{th}$ percentile.

As can be determined, EPA's recommended CT and RME consumption rates for recreational fishers are within the plausible range of reasonable consumption rates for a water body the size of the Lower Willamette River, and any reassessment of the available literature will not result in an appreciable change to the overall consumption rates, and thus the overall assessment and the conclusions of the assessment. Given the uncertain knowledge of actual consumption practices in Portland Harbor, the rates currently used in the BHHRA are within any plausible range of uncertainty, and further re-evaluations and calculations would only yield similar results.

As with the consumption rates used to represent recreational fishers, the recommended consumption rate of 142 g/day for high-consuming, or subsistence fishers is well within the range of plausible values. As noted in EPA's guidance for Ambient Water Quality Criteria (Tab 42), 142 g/day is considered an average consumption rate for non-tribal subsistence fishers, and the corresponding adjusted 99$^{th}$ percentile consumption rate for finfish (consumers only) is 217 g/day and 72 g/day for locally-harvested fish (Exhibit 18). Hence, using a rate of

142 g/day accounts for the myriad of uncertainties associated with actual consumption rates for Portland Harbor, including the amount of resident fish consumed. Any reevaluation of risk assuming slightly different consumption rates would not yield notably different results.

B. EPA's revised BHHRA text on exposure assessment, risk characterization, and uncertainty sections of the BHHRA regarding the drinking water scenario and clam consumption scenario is reasonable and appropriate for the Portland Harbor Superfund Site and is consistent with the NCP and EPA guidance.

The Respondents dispute EPA's June 2012 directed redline that deleted relevant context information for the domestic water use and clam consumption scenarios from everywhere they claim it should be stated in the BHHRA. Please note that relative to the context information at issue, EPA did not delete the language entirely from the June 2012 modified risk assessment; the language is retained in the uncertainty section (Section 6) of the BHHRA. The Respondents acknowledge that the September 17, 2012 draft contains some of the context information they want, but not all.

The Respondents assert that critical information is lacking from the Exposure Assessment Discussion in Section 3 at 3.2.1.8 by noting that the September 17, 2012 redline would "direct the LWG to include the following in the description of the domestic drinking water exposure scenario in Section 3.2.1.8:

> Although there are currently no known uses of the Lower Willamette River as a source of drinking water, public and private use of the Willamette River as a domestic water source is a designated beneficial use by the State of Oregon. Hence, use of surface water as a source of household water was assessed as a potentially complete pathway."

The Respondents assert the information is inaccurate by omission in that it infers that water will be used untreated because State rules require pretreatment. No reasonable reader could make this inference because Section 1 of the BHHRA, page 25 of the September 17, 2012, version, explains that a baseline risk assessment should evaluate human health risks associated with contamination in the absence of remedial actions or institutional controls (such as State pretreatment requirements). Additionally, Section 3.2, page 44 of the September 2012 version, states specifically in relation to the private or public use of surface water as a drinking water source that "this baseline risk assessment evaluates exposures assuming no institutional controls, such as obtaining a permit for use of surface water."

Oregon's water quality standards for the Lower Willamette River establish that domestic water supply is a designated use, thus, the lower Willamette River is to be protected for such use from point and non-point sources. The Respondents are focused on a notation in

Oregon's water quality standards that indicates that adequate pretreatment is assumed relative to the designated use of domestic water supply, and contend that notation must have some legal significance such that the exposure assessment description in Section 3.2.1.8 is inaccurate without mentioning it. Attached as Exhibit 14 is a copy of the excerpt from Oregon's promulgated water quality standards. First, the Oregon water quality standards are not independently enforceable, thus the notation itself certainly is not. An NPDES permit, water quality certification or other type of license issued by Oregon's Department of Environmental Quality is required to enforce water quality standards. Secondly, following Respondents' logic, every other regulation for purveyors of drinking water in the State of Oregon would also need to be mentioned in Section 3.2.1.8, such as the Oregon Health Authority's administrative rules for public water supplies found at OAR 333-061-005. There likely are other rules and regulations that would relate to the use of surface water as a drinking water supply. However, the point is that a baseline risk assessment assesses risk assuming the receptor is exposed to the surface water and contamination in such surface water in absence of any regulation.

Following this same logic, EPA believes there is no statement "inaccurate by omission" in Section 3.3.6 regarding consumption of shellfish, including Asian clams because it fails to note that harvesting Asian clams is prohibited by State law. By definition, the baseline risk assessment assesses this exposure pathway assuming no existing institutional controls.

Let's be clear, the Respondents and EPA only disagree about where the discussion of a couple of Oregon Statutes should be presented in the BHHRA, not the omission of said language entirely. EPA modified the text of the draft BHHRA to make the document clear, transparent, and defensible. We believe we achieved that goal. We have agreed to make reasonable changes that Respondents have requested, while maintaining the clarity we sought to obtain. EPA's position on this issue should be upheld.

1. EPA's modifications are consistent with guidance.

Nowhere in Section 5.3.3 of the Exposure Assessment Guidelines is "context" discussed. This section notes that exposure assessments can be used to assess the impact of possible control actions by changing the assumptions to represent conditions that would exist after the action is implemented and reassessing the exposure and risk. However, such an evaluation in a baseline assessment would be inconsistent with EPA's stated definition of a "baseline" risk assessment. RAGS Part A defines a baseline assessment as "an analysis of the potential adverse health effects (current or future) caused by hazardous substance releases from a site in the absence of any actions to control or mitigate these releases (i.e., under an assumption of no action)" (*see* Tab 1, RAGS Part A, Pages 1-4) It also states that the exposure assessment should consider the general physical

characteristics of the site and characteristics of the population that may influence exposure, such as location relative to the site, activity patterns, and the presence of sensitive subpopulations. The Respondents assert that it is "important to provide the RPM or risk manger with information related to the likelihood that the assumed conditions will occur to allow interpretation of a conditional risk estimate in the proper context." (Opening statement, p 26). However, their cited text from RAGS Part A is from Section 8.4, Assessment and Presentation of Uncertainties. More specifically, it is found in Section 8.4.1, which discusses presentation of site-specific uncertainties, including those associated with the definition of the physical setting. Accordingly, EPA believes that presenting this relevant information in the uncertainty section is entirely consistent with guidance, rather than contrary to EPA guidance as the Respondents assert.

The Respondents claim the risk assessment for the Lower Fox River (*see* Tab 44) excludes the domestic drinking water entirely because the Lower Fox River is not used as a primary drinking water source. Yet, contrary to this assertion, the risk assessment notes at 3861 (p 5-5) that the receptors evaluated includes "drinking water users," and at 3863 (p 5-7) that "Drinking water users are individuals that use water taken directly from the Lower Fox River as a source of drinking water." A detailed description of the process used to evaluate exposure via ingestion, dermal contact, and inhalation due to use of surface water as a source of drinking water and other household water source is provided at 3871-3874 (pp 5-15 to 5-18).

In a similar vein, there is nothing in guidance or policy that compels EPA to include in Section 3.3.6 information noting that harvest of Asian clams is illegal. While Asian clams are now the predominant shellfish present, they are not the only species found, and the exposure assessment is clear in its intended purpose of an evaluation of the harvest and consumption of shellfish, including Asian clams, in the absence of any existing prohibitions. Indeed, information cited in the risk assessment and in other sources (see Exhibit 15) indicates that the existing prohibition regarding harvesting and possession of Asian clams is largely ineffectual.

As noted previously, EPA's interpretation of its guidance is that information relevant to other than baseline conditions is most appropriately discussed in the presentation of uncertainties, as clearly described in Section 8.4 of RAGS Part A (*see* Tab 1). The Respondents express concerns this information has been "moved back to the uncertainty section (Section 6). EPA has shown that guidance and policy clearly state that the uncertainty discussion is the appropriate place for this supplemental information in the BHHRA. EPA notes that, at several instances during the informal dispute meetings, EPA offered to allay some of the

Respondents' concerns by presenting the uncertainties information in each relevant section of the BHHRA, rather than as a stand-alone discussion of all uncertainties in Section 6, which was the Respondents' original format. We note that a section-by-section uncertainties format is consistent with the suggested outline for a baseline risk assessment report presented as Exhibit 9-1 in RAGS Part A (*see* Tab 1).

2. The EPA's interpretation of the RAGs Part A and of the meaning of an institutional control in the context of the BHHRA is appropriate relative to assessing baseline risks.

There is no definition or discussion in RAGs Part A of the meaning of institutional controls. Additionally, there is no definition of institutional controls in CERCLA or the NCP.[16]

Risk assessments and risk assessment guidance relate to a scientific assessment of risk from exposure to contamination prior to any determination that remedial action is necessary. Thus, the perspective on what an institutional control is for purposes of a risk assessment is not necessarily the same as what an institutional control is as a component of a remedial action. Some controls that may be relevant to a particular exposure scenario may later become institutional controls used to implement a remedy, but many other types of controls may not be appropriate as a remedy component, such as Oregon laws requiring water purveyors to do pretreatment.[17]

C. A brief, concise executive summary consistent with the Formal Dispute Decision is appropriate for the final BHHRA, but not a separate conclusion section; the EPA always intended for there to be a Table of Contents.

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[16] The NCP discusses institutional controls and program management expectations, but does not define the term. *See* NCP 300.430(a)(1)(iii)(D).

[17] As a side note, it would be inconsistent with CERCLA if EPA were to agree that "pretreatment" of water from the Willamette River for domestic use includes treatment of hazardous substances released at the Portland Harbor Site and, thus, it's the purveyor of the water that should have to remediate the contaminants. CERCLA mandates that any remedial action attain Safe Drinking Water standards and water quality criteria established under the Clean Water Act. 42 U.S.C. §9621(d)(2)(A). Thus, the discussion of treatment is further irrelevant because the treatment that would occur absent releases of hazardous substances would typically be for bacteria, solids, and minerals (such as iron, manganese, and sulfur). If the discussion in the exposure assessment (Section 3) of the BHHRA includes such language as the Respondents request, the reader could misinterpret that there must be no risk from domestic water use since it will all be treated without CERCLA action, or that the PRPs would not be required to remediate any contaminants because the purveyor would be required to remove any objectionable contaminants.

The May 2, 2011, draft final BHHRA had a 17 page executive summary. Further, the BHHRA is an appendix to the Remedial Investigation report, which summarizes the BHHRA in Section 8. EPA determined that the executive summary was far too lengthy and redundant considering there was a similar summary in Section 8 of the RI report. However, EPA agrees that a more concise executive summary (on the order of three pages) that is consistent with the formal dispute decision would be appropriate for the final BHHRA. EPA notified the Respondents of this intent on September 14, 2011 (Exhibit 4).

EPA does not see a need to have both a Summary section and a Conclusions section in the BHHRA. The conclusions of the BHHRA are presented in the Summary (Section 7) of the document and EPA has determined that this discussion is sufficient. There is no need for two subsequent sections in the BHHRA that discusses the same information.

EPA had always intended for there to be a table of contents in the document and is unclear why the Respondents are now raising this issue. This issue was not raised during the informal dispute resolution discussions that took place between July and September. All versions of the document, including the latest version, *see* Respondents' Exhibit 1, have a placeholder for a table of contents. EPA removed the details of the table of contents from the document since the modifications being made to the document were playing havoc on the automatically updated table of contents, *see* Tab 16.

V. IT IS INAPPROPRIATE TO AMEND THE AOC THROUGH THE FORMAL DISPUTE PROCESS, BUT IF ITS DETERMINED TO BE APPROPRIATE RELIEF FOR THIS DISPUTE, THEN ON THE MERITS NO AMENDMENT TO THE AOC IS NECESSARY.

A. The Respondents are seeking to amend the terms of the AOC through the dispute process which is not the appropriate or relevant process.

"[T]he LWG requests that the ECL Director commit to meet with the LWG Senior Management and to establish a mutually-agreed upon set of documented protocols to guide a better working relationship . . . .:" page 33 of Opening Statement. We understand the Respondents dispute how EPA modified the BHRRA, but the relief they seek is not appropriate as a resolution to a dispute.

1. Amending the terms of the AOC is not within the scope of the dispute resolution process provided by the AOC.

Section XVIII. Paragraph 1 of the AOC provides: ". . . If Respondents object to any EPA notice of disapproval or requirement made pursuant to this Consent Order, Respondents shall notify the EPA Project Coordinator in writing . . . of their objection(s) . . . of the disapproval notice or requirement." Respondents can dispute how and why EPA modified its deliverable, but seeking a dispute decision agreeing to documented protocols to guide a future working relationships is an amendment to the AOC, not a resolution of a

"disapproval or requirement made" under the order. Nowhere in the dispute resolution provisions does it say the AOC can be amended through that process. That is because the AOC includes a specific amendment section, e.g., Section XXVII.

Section XXVII of the AOC provides that the way to amend the AOC is through a mutual agreement of EPA and the Respondents. Amendments shall be in writing and shall be effective when signed by EPA's delegated authority. Section XXVII does not reference Section XVII, the dispute resolution process, as an alternative means to amend the AOC, nor does it provide that any other process can be used to amend the AOC.

The dispute resolution process is not a consensus process such as required by an amendment to an agreement. Rather, it is an administrative dispute process at the end of which the Director of the Office of Environmental Cleanup ("ECL") makes the final decision. Section XVIII, Paragraph 1, clearly provides that the ECL Director's determination is EPA's final decision and the Respondents shall proceed in accordance with EPA's final decision regarding the matter in dispute, regardless of whether the Respondents agree with the decision. The Respondents' request that the ECL Director meet with the Senior Management to establish a documented set of protocols by its nature is not a dispute resolution issue, but rather an AOC amendment matter.

2. A meeting to discuss relationships and how to work better together is appropriate outside of the dispute process.

For all of the reasons stated above, the Director should determine that he cannot agree to meet and establish documented protocols on better working relationships through this dispute process. However, a meeting of the Director and EPA staff with representatives of the Respondents to discuss their unspecified issues and requests should occur outside of the dispute process. In fact, EPA staff believes a meeting to discuss how we can work more productively and efficiently in the future would be a good idea. With that said, the Director should clarify for the Respondents that any discussion will not include relinquishing any enforcement authority.

B. No amendment to the AOC or the review, comment, and approval process is appropriate or necessary.

If the Director determines that meeting on protocols can be a matter addressed through the dispute process, EPA's actions related to the second draft BHHRA were in compliance with its reserved rights and authorities under the AOC, CERCLA, and NCP, and there is no reason to consider amendments to the AOC as detailed in Section II. of this Response. The Respondents did not provide a specific proposal regarding the "documented protocols" it desires. However, they have made clear they do not like that EPA modified their second draft BHHRA without conferring with them about the reasons for modifying the document or the specific modifications we were making. As detailed above, EPA was under no requirement to notify the Respondents

prior to modifying the BHHRA, nor was EPA required to discuss the basis for our modifications prior to providing them the modified BHHRA. Nonetheless, EPA in fact did notify Respondents as far back as July 2011 that we were modifying the document and we told them generally the problems we saw that was leading to us do the modifications. See Tabs 18 and 19.

The EPA has had numerous and extensive interactions with the Respondents as part of the process of review and approval of a multitude of major and minor project deliverables over the past 10 years. The typical process of reviewing deliverables, providing comments, clarifying comments, directing changes and resolving disagreements over comments and directed changes included frequent meetings between EPA and the Respondents technical staff and project managers and required significant investment of time and staff resources. The issues were often technically complex and both parties attempted to work collaboratively to fully understand and resolve areas of disagreement.

Numerous sampling plans, technical evaluations, summary reports, work plans, and other precursors to the RI and risk assessment reports were completed and approved in this manner. For major deliverables, the process often involved use of comment resolution tables to methodically clarify, track, and narrow the list of disagreements. In many cases, agreements were reached through the comment resolution process, the Respondents modified the documents in accordance with EPA's comments and direction, and documents were subsequently approved. For other deliverables, EPA needed to "cut off" unproductive meetings and conversations after a period of time when it became apparent that agreements on certain issues could not be reached and direct the Respondents to make the necessary changes. The EPA typically was more directive in requiring changes after allowing the Respondents the opportunity, or in some cases multiple opportunities, to modify unacceptable documents to correct deficiencies. Up to this point, the Respondents have not disputed EPA's direction, although the Respondents too have made it clear on the record several times that, although they would perform required work, they still disagreed with EPA's direction.

The reality is that EPA has not taken a heavy hand throughout the RI/FS process, and has sought to work cooperatively to the extent possible. In doing so, the Remedial Project Managers (RPMs) at times through the process may have agreed to a path forward demanded by the Respondents to keep the RI/FS and risk assessment moving forward. However, at the time the full ramifications and consequences of those agreements became apparent in the second draft BHHRA, a correction in course was needed and EPA modified the text of the BHHRA to make those corrections. Such is the right and in fact duty of the EPA as the delegated authority to make remedy decisions under CERCLA. Another reality the Respondents must face is that changes in course and perceived agreements with the EPA RPMs may very well happen until the Record of Decision is issued. As the RI/FS and preferred alternative are reviewed by Regional management, the Office of Regional Counsel, and EPA Headquarters, changes may occur at any time through that review process. Also, statutory mandated public participation too may result in changes to the proposed remedy or underlying technical work performed by the Respondents.

Although the agency should agree to meet with the Respondents to discuss their proposals, there will be certain constraints on the nature and scope of amendments to the review and approval process. Just from the tenor and statements made in their Opening Statement, the nature of the amendments the Respondents are seeking appear problematic under the CERCLA statutory scheme. This is because, while the AOC is on consent, CERCLA is not a voluntary cleanup program. To assure legal documents comply with the law and regulations and provide consistency in process and enforcement, the EPA depends on nationally issued model documents, most relevant here, model administrative consent orders. Although the Respondents have not said what protocols they seek, it is likely amendments to the AOC review and approval procedures will need to be thoroughly vetted through the Office of Regional Counsel in consultation with the Office of Site Remediation Enforcement in EPA Headquarters.

## VI. CONCLUSION

The RI/FS has been in process for 12 years in large part due to the complexity of the site, but also because additional time and resources that have been required in seeking agreement with the Respondents. Seeking consensus is a time consuming process, especially when so many parties are involved in the process. The record is clear that EPA has sought to cooperatively work through technical issues along the way with the Respondents. The AOC, as well as the statute, provides EPA with the ultimate approval and decision-making authority. The Respondents, in signing the AOC, get to participate in the process and when they disagree with comments and directions by EPA, the AOC provides them with a dispute resolution process which elevates the issue for final decision to a high management level within the Office of Environmental Cleanup.

Now that the risk assessments, RI Report and FS Reports are moving to completion, it is imperative these fundamental documents that will inform and support the cleanup decisions for the Portland Harbor Superfund Site be acceptable to EPA, comply with CERCLA, the NCP, and EPA guidance, and are documents that the EPA can defend in selecting a remedy for this site.

Rather than view the process as broken, the process actually worked as the AOC was designed. EPA modified the BHRRA in a way it could approve it more quickly. Even though Respondents chose to dispute the modifications, the informal dispute process led to reaching many agreements on the BHHRA and narrowing down those issues the Respondents sought to take to the Director. There are major documents under review right now, the Baseline Ecological Risk Assessment, the second draft RI report, and the first draft FS. How the EPA responds to those documents will be in compliance with our authority under the AOC and CERCLA with the overall goal of achieving acceptable documents in as timely a manner as possible.

Based on our responses and the administrative record created for this dispute, EPA respectively requests the Director to make the following decisions:

1. Uphold EPA's determination under the AOC that Respondents failed to produce a deliverable of acceptable quality, or otherwise failed to perform in accordance with the

requirements of the AOC because they did not adequately address all of EPA's comments;

2. Adopt EPA's positions, as presented in this response, on the appropriate Reasonable Maximum Exposure and Central Tendency Exposure Scenarios for recreational and subsistence fishers for incorporation, as appropriate, into the text and tables and figures of the final BHHRA;
3. Agree with EPA's positions on exposure scenario and uncertainty language regarding domestic water and clam consumption (which would require no additional changes to the draft BHHRA text);
4. Agree with EPA's positions regarding the Executive Summary, Table of Contents, and Conclusion sections;
5. Adopt the revised BHHRA, dated September 17, 2012, [Respondents' Exhibit 1 and EPA's Exhibit 13] which incorporates a majority of the resolutions reached between Respondents and EPA as of September 14, 2012, and require that the resolutions of the disputed technical issues (2, 3, and 4, above) from this dispute will be incorporated, if necessary, by EPA into the final document[18]; and
6. Determine that the Respondents' request to establish protocols for better working relationships would be an amendment to the review and approval process and enforcement provisions of the AOC and, thus, is not relief that can be addressed through the dispute resolution process.

[18] EPA agrees that substantial progress was made during the informal dispute process and that Tables 1 and 2 generally reflect the specific issues raised by Respondents that they and EPA reached some form of resolution on. But it is only the specific agreed-upon language reflected in the red-lined text of the Sept 17, 2012 BHHRA that has been agreed to so far. Thus, EPA does not believe it is necessary or appropriate for the Director to approve Tables 1 and 2 themselves.